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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,863	12/29/2004	Robert Allan Phillips	14450.8USWO	9292

23552 7590 02/05/2008

MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,863	PHILLIPS, ROBERT ALLAN	
	Examiner	Art Unit	
	Kennedy Schaetzle	3766	

CT

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Koestner et al. (Pat. No. 5,139,020).

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Koestner et al..

Regarding claim 3, because the system of Koestner et al. is implanted and uses feedback of flow output to automatically adjust the timing of pacing events, it can be said that the device necessarily performs the method of claim 1 under a variety of different operating conditions due to the natural activity of the implant patient over the course of the day (which for all intensive purposes for a typical human would include walking and/or running). In any event, Koestner et al. teach that cardiac output naturally varies with exercise (col. 14, lines 37-68). Clearly a pacer patient with a rate responsive

device that is exercising (e.g., walking or running) requires the device to accurately account for the increased activity by adjusting the pacing rate to provide the necessary cardiac output –just as a healthy heart would. It is also well known that when fitting a pacer device to a patient, the effectiveness of the pacer in accounting for physical activity is typically tested by requiring the patient to perform exercise. It would in fact be unthinkable to implant a pacer without testing the response of the implant to induced cardiovascular stress. Those of ordinary skill in the art recognizing the relationship between exercise and cardiac output and recognizing the importance of testing the pacer's response to a variety of expected conditions, would have seen the obviousness of tuning the pacer to account for exercise such as walking and/or running.

Regarding claim 4, because the system of Koestner et al. is implanted and uses feedback of flow output to automatically adjust the timing of pacing events, it can be said that the device necessarily performs the method of claim 1 under a variety of different operating conditions including those associated with drug therapy. In other words, if a drug were to have an affect on the pacer implant patient's cardiac output, the pacer system of Koestner et al. would automatically and inherently take this into account and attempt to remedy a lower output, for example, by increasing the pacing rate. In any event, those of ordinary skill in the art recognizing that various drugs may affect cardiac output and/or blood flow, would have readily understood the importance of testing a pacing device that is designed to affect changes in cardiac output by testing the device in the presence of cardiac output affecting drugs expected to be used by the patient in order to avoid unintended or potentially dangerous consequences. To

therefore test the pacer under a number of different pharmalogical conditions for the patient would have been considered obvious by those of ordinary skill in the medical arts.

5. Claims 2, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koestner et al..

Regarding claims 2 and 5, Koestner et al. do not utilize a transcutaneous CW Doppler signal and thus do not disclose monitoring means that are noninvasive. Koestner et al., however, do disclose that it is known in the art to use noninvasive Doppler to measure blood flow parameters, but that prior artisans have not used the signal to control cardiac functions such as pacing (col. 5, lines 31-43). While Koestner et al. go on to disclose an invasive CW Doppler monitor, those of ordinary skill in the art given the disclosure of Koestner et al. that noninvasive measurements of cardiac output can be made, would have had a reasonable expectation that tuning a pacer with a noninvasive Doppler monitoring means would have met with success. Anyone looking to limit the complexity of the implant, or looking to expand the signal processing capabilities and speed beyond that capable with the limited processing power of the pacer and concomitantly reduce implant size and energy consumption, would have seen the obviousness of trying the tuning procedure with a noninvasive monitoring means.

Regarding claim 6, note among other recitations, col. 19, lines 7-24.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy Schaetzle/
Primary Examiner, Art Unit 3766

KJS
January 31, 2008